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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,105	03/31/2004	James B. Hunt	8627- 431 (PA-5498-RFB)	6585
757 7590 05/16/2007 BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			EXAMINER POUS, NATALIE R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,105	Applicant(s) HUNT, JAMES B.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/17/05, 7/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Regarding the claim objections

Examiner acknowledges amendment to claim 1, and thus withdraws the previous objection.

Regarding the 35 USC 112 Rejection

Examiner acknowledges amendment to claim 7, and thus withdraws the previous rejection under 35 USC 112.

Regarding Kuwahara

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Regarding Lentz

Applicant argues that Lentz fails to disclose all the limitations of claim 1. More specifically, applicant argues that Lentz fails to teach a unitary stent structure or radial openings extending there through. Examiner respectfully disagrees. Regarding the limitation wherein the stent-graft assembly comprises at least one unitary stent structure, examiner notes that since the claim language of claim 1 recites a stent-graft assembly **comprising**, a prior art reference must include at least the limitations as set forth by the claim. Examiner asserts that each ring structure (28) of Lentz is in fact a unitary stent structure, and thus meets that limitation of the claim. Regarding the limitation wherein the device comprises first and second radial openings being axially and circumferentially defined by a plurality of struts, after further consideration, examiner sustains that Lentz does in fact teach this limitation. With regards to Lentz,

examiner interprets a radial opening as the space between stent members 28. It is clear based on figure 1 that the radial opening is defined radially by the struts of the stent members, however examiner asserts that the struts also define radially the opening. Otherwise, it could be said that the opening extends infinitely, since this is not the case (it is clear from applicants disclosure that the radial openings are confined to the device) examiner asserts that the outer circumference of the struts of two stent members defining a space there between defines the openings circumferentially.

Regarding the combination of Lentz and Buirge

Applicant argues that there is not motivation or suggestion to combine these two references. Examiner respectfully disagrees. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Buirge teaches the use of natural tissue as graft material in order to provide advantages, in this case allowing the graft material to release a therapeutic material, and further the use of a graft made of natural tissue allows cellular re-growth of the endothelium to protect against tissue flaps and exposure of necrotic or atherosclerotic tissue to blood, providing biological protection. Buirge further states "both the biological and physical advantages as described herein can not be provided

by synthetic sleeves as Dacron or PTFE" (paragraph 45). Thus, the use of natural material for the graft layer provides a clear advantage over the synthetic material of Lentz, and thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lentz with natural material as taught by Buirge in order to provide these advantages.

Election/Restrictions

Newly submitted claim 35 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: This application contains claims directed to the following patentably distinct species:

Species 1: fig. 1, movement allowed in plural directions

Species 2: fig. 3, movement restricted to one direction

The species are independent or distinct because they require different technical features, for instance species 1 simply requires that attached portions be located within the radial openings, while species 2 requires specific placement of the attached portions to restrict movement.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 35 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

§ 36 are
Claims 1-11, 13, 14 and 16-19^{§ 36 are} rejected under 35 U.S.C. 102(b) as being anticipated by Lentz et al. (US 5843166).

Regarding Claim 1, Lentz teaches a stent-graft assembly, comprising: at least one unitary stent structure (28) comprising a luminal surface and an abluminal surface and having at least a first radial opening and a second radial opening (between stent portions 28') said first and second radial openings being axially and circumferentially defined by a plurality of struts, said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface, wherein said first and second radial openings are spaced apart along a first direction; a first graft layer (22') disposed along at least a portion of said luminal surface of said stent structure thereby fully covering luminal sides of said first and second radial openings; a second graft layer (12') disposed along at least a portion of said abluminal surface of

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said stent structure thereby fully covering abluminal sides of said first and second radial openings (fig. 3); a first attached area securing said first graft layer and said second graft layer together through a portion of said first radial opening (fig. 3), wherein a first unattached margin (30a') whereby said first and second graft layers are not secured to each other being disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a portion of said second radial opening (30b'), wherein a second unattached margin whereby said first and second graft layers are not secured to each other being disposed between said second attached area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction and on a same side of said first and second attached areas, thereby allowing said first and second graft layers to move along said first direction relative to said stent (Column 3, proximate lines 42-45)

Regarding Claim 2, Lentz teaches the stent-graft assembly according to claim 1, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. 3.

Regarding Claim 3, Lentz teaches the stent-graft assembly according to claim 1, wherein said first direction is axial (see fig. 3).

Regarding Claim 4, Lentz teaches the stent-graft assembly according to claim 1, wherein said first direction is circumferential (fig. 3).

Regarding Claim 5, Lentz teaches the stent-graft assembly according to claim 1, wherein said first attached area is positioned adjacent another edge of said first radial opening and said second attached area is positioned adjacent another edge of said second radial opening (fig. 3), said first and second attached areas thereby being disposed on opposite sides of said struts, whereby said first and second graft layers are restricted from moving along a second direction relative to said stent.

Regarding Claim 6, Lentz teaches the stent-graft assembly according to claim 5, wherein said first direction is axial and said second direction is circumferential (fig. 3)

Regarding Claim 7, Lentz teaches the stent-graft assembly according to claim 1, wherein said first unattached margin extends peripherally all around said first unattached margin and said second attached area extends peripherally all around said second attached area (fig. 3).

Regarding Claim 8, Lentz teaches the stent-graft assembly according to claim 7, wherein a size of said first attached area is less than a size of said first unattached margin (30a') and a size of said second attached area is less than a size of said second unattached margin (30b'), see fig. 3.

Regarding Claim 9, Lentz teaches the stent-graft assembly according to claim 1, wherein: a third unattached margin (30c') whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening; a fourth unattached margin whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached

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margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (fig. 3), it is noted that there is sufficient space in the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. 3.

Regarding Claim 10, Lentz teaches the stent-graft assembly according to claim 9, wherein a size of said first attached area (24') is less than a size of said third unattached margin and a size of said second attached area is less than a size of said fourth unattached margin (see fig. 3).

Regarding Claim 11, Lentz teaches the stent-graft assembly according to claim 1, wherein said first graft layer (22') covers substantially all of said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Regarding Claim 13, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding (Column 5, proximate lines 40-45).

Regarding Claim 14, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 16, Lentz teaches the stent-graft assembly according to claim 1, wherein said first and second attached areas are attached by thermal bonding

(Column 5, proximate lines 40-45); and said first and second graft layers comprise a synthetic polymer (Column 3, proximate lines 64-67).

Regarding Claim 17, Lentz teaches the stent-graft assembly according to claim 16, wherein: a third unattached margin whereby said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening (30c'); a fourth unattached margin whereby said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and said third and fourth unattached margins are oriented along a second direction, thereby allowing said first and second graft layers to move along said second direction relative to said stent, said second direction being different than said first direction (fig. 3), it is noted that there is sufficient space in the unattached margins for the stent structure to move both longitudinally and circumferentially, see fig. 3.

Regarding Claim 18, Lentz teaches the stent-graft assembly according to claim 17, wherein a size of said first attached area is less than a size of said first unattached margin and a size of said third unattached margin and a size of said second attached area is less than a size of said second unattached margin and a size of said fourth unattached margin (fig. 3).

Regarding Claim 19, Lentz teaches the stent-graft assembly according to claim 18, wherein said first graft layer (22') covers substantially all of said luminal surface of said stent structure and said second graft layer (12') covers substantially all of said abluminal surface of said stent structure.

Regarding Claim 36, Lentz teaches a stent graft assembly comprising: a stent structure (28) comprising a luminal surface and an abluminal surface and having at least a first radial opening and a second radial opening, said first and second radial openings extending through said stent structure between said luminal surface and said abluminal surface, wherein said first and second radial openings are spaced apart along a first direction; a first graft layer (22') disposed along at least a portion of said luminal surface of said stent structure thereby fully covering a luminal side of said first and second radial openings; a second graft layer (12') disposed along at least a portion of said abluminal surface of said stent structure thereby fully covering an abluminal side of said first and second radial openings; a first attached area securing said first and second graft layers together through a portion of said first radial opening, wherein a first unattached margin (30a') in which said first and second graft layers are not secured to each other is disposed between said first attached area and an edge of said first radial opening; a second attached area securing said first graft layer and said second graft layer together through a portion of said second radial opening, wherein a second unattached margin (30b') in which said first and second graft layers are not secured to each other is disposed between said second attached area and an edge of said second radial opening; and wherein said first and second unattached margins are oriented along said first direction and on a same side of said first and second attached areas, thereby allowing said first and second graft layers to move along said first direction relative to said stent (fig 3) and wherein said first unattached margin extends peripherally all around said first attached area and said second unattached margin

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extends peripherally all around said second attached area (it is noted that these are inherent features as defined by the attached and unattached areas).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15 and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Buirge et al. (US 2001/0034550).

Lentz teaches all limitations of preceding dependent claim 1 and claims 24-34, as previously described with respect to claims 1-11, 13, 14 and 16-19, but fails to teach wherein the graft layers comprise small intestine submucosa attached by thermal bonding. Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa in order to provide a graft material that can hold and release therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the device of Lentz as taught by Buirge in order to provide a graft material that can hold and release therapeutic material.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Lombardi et al. (US6579314).

Lentz teaches all limitations of preceding dependent claim 1, but fails to teach wherein the first and second attached areas are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz in view of Buirge, and further in view of Lombardi. Lentz teaches all limitations of preceding dependent claims 1, 16 and 17, and further all limitations of claims 21-23 as described previously, but fails to teach wherein the graft layers comprise small intestine mucosa and are attached using sutures.

Regarding the limitation wherein the graft layers comprise small intestine mucosa, Buirge teaches a stent covered by two grafts, wherein the grafts are formed of submucosa attached by thermal bonding (paragraphs 53-60) in order to provide a graft material that can hold and release therapeutic material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of

Lentz as taught by Buirge in order to provide a graft material that can hold and release therapeutic material.

The combination of Lentz and Buirge fails to teach wherein the graft layers are attached using sutures. Lombardi teaches a covered stent having a luminal and abluminal covering sutured together (Column 5, proximate lines 27-30). It would have been an obvious matter of design choice to attach the graft members of Lentz with sutures as taught by Lombardi since applicant has not disclosed that suturing as opposed to welding serves any particular purpose or provides any advantage.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tan-Uyen (Jackie) Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
5/10/07


JACKIE TAN-UYEN HO
PRIMARY EXAMINER
5/11/07